

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|-------------------|--------------------|
| Application No.: | 10/695,295 |
| Applicant: | Gonzales et al. |
| Filed: | October 28, 2003 |
| TC/A.U.: | 3763 |
| Confirmation No.: | 4188 |
| Examiner: | Quynh-Nhu Hoang Vu |
| Docket No.: | A-2966-AU |
| Customer No.: | 21378 |

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. 41.37

Sir:

In accordance with the Notice of Appeal filed September 11, 2009, Applicants submit this Appeal Brief, which is timely filed by November 12, 2009 because November 11, 2009 falls on a holiday.

TABLE OF CONTENTS

| | |
|--|----|
| Real Party in Interest..... | 2 |
| Related Appeals and Interferences..... | 2 |
| Status of Claims | 2 |
| Status of Amendments | 2 |
| Summary of Claimed Subject Matter..... | 2 |
| Grounds of Rejection to be Reviewed on Appeal..... | 4 |
| Argument | 6 |
| Claims Appendix | 14 |
| Evidence Appendix..... | 18 |
| Related Proceedings Appendix | 19 |

I. REAL PARTY IN INTEREST

The real party in interest is Applied Medical Resources Corp.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for this application.

III. STATUS OF CLAIMS

Claims 1, 2, and 4–15 are pending. Claims 11–15 are withdrawn. Claims 1, 2, and 4–10 stand rejected. Claims 3 and 16–25 have been canceled. Claims 1, 2, and 4–10 are appealed.

IV. STATUS OF AMENDMENTS

No amendments were filed after the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

None of the appealed claims is a means- or step-plus-function claim.

Claims 1, 6, and 10 are independent claims that provide a surgical valve **50** useful, for example, in procedures on the urinary tract including visualizing the interior of the kidney **18** using a ureterscope **34**. FIGS. **1** and **2**, Substitute Specification at p. 10, ll. 3–4. Irrigating and aspirating with saline improves visualization; however, retrograde flow of saline can contaminate a surgical site. Substitute Specification at p. 10, ll. 4–9. As illustrated in FIG. **2**, disposing a surgical valve **50** at an exit port **43** of the ureterscope **34** prevents this route of contamination. Substitute Specification at p. 10, ll. 9–11. In particular, the surgical valve **50** provides a zero seal in the absence of an instrument extending therethrough, and an instrument seal in the presence of an instrument, for example, a guidewire **32**. *Id.* Embodiments of the surgical valve **50** accommodate retrograde insertion of an instrument, for example, a guidewire **32**. Substitute Specification at p. 10, ll. 16–20. After removal of the guidewire **32**, instruments for capturing and removing stones **25** may be forwardly inserted through the valve **50**. Substitute Specification at p. 11, ll. 1–6, 14–16.

With reference to the embodiment illustrated in FIGS. **6** and **7**, independent claim 1 provides a surgical valve **50a** comprising a proximal housing portion **74a** and a distal housing portion **76a**, which together, define a gel cavity **78a**. Substitute Specification at p. 13, l. 19– p.

14, l. 3. A seal material **81a** comprising a gel **72a** is disposed in the gel cavity **78a**. *Id.* The gel **72a** is non-compressible, thereby converting pressure applied thereon into a seal. Substitute Specification at p. 15, ll. 5–9. A proximal guide tube **123**, which facilitates antegrade instrument insertion, extends from the proximal housing portion **74a**. Substitute Specification at p. 14, ll. 12–14. A distal guide tube **85a**, which in the illustrated embodiment, is dimensioned as a Luer fitting **85a**, extends from the distal housing portion **76a** and facilitates retrograde instrument insertion. Substitute Specification at p. 13, l. 19–p. 14, l. 1. A distal portion **127** of the proximal guide tube **123** extends into the gel cavity **78a**. Substitute Specification at p. 15, ll. 3–7. The proximal housing portion **74a** is adjustably movable relative to the distal housing portion **76a**, applying pressure on the gel **72a**, and thereby generating a locking force on an instrument extending therethrough. Substitute Specification at p. 17, l. 17–p. 18, l. 1 (FIG. 12).

Claims 2, 4, and 5 are dependent on claim 1.

Claim 2 recites a Luer lock **87a** coupled to the distal housing portion **76a**.

Claim 4 recites an axial channel **101a** through the gel **72a**, and the proximal guide tube **123** contacts the gel **72a** around the axial channel **101a**. Substitute Specification at p. 14, ll. 4–5; p. 15, ll. 3–5.

Claim 5 recites that the gel **72a** does not form a circumferential seal with the distal housing portion **76a** in the absence of pressure applied by the proximal guide tube **123**. Substitute Specification at p. 15, ll. 3–9.

Independent claim 6 provides a surgical valve **50** comprising a subassembly comprising a first housing portion **76a** defining a gel cavity **78a**, and a seal material **81a** including a gel **72a** disposed in the gel cavity **78a**. FIG. 6. The seal material **81a** comprises a node **116** and an axial channel **101a** in an open state. Substitute Specification at p. 14, ll. 4–6; p. 14, ll. 19–20. A second housing portion **74a** in juxtaposition with the first housing portion **76a** applies force on the seal material **81a**, thereby closing the axial channel. Substitute Specification at p. 15, ll. 1–9.

Claims 7–9 are directly or indirectly dependent on claim 6.

Claim 7 recites a circumferential seal between the seal material **81a** and the first housing portion **76a**. Substitute Specification at p. 15, ll. 7–9.

Claim 8 is dependent on claim 7 and recites that the second housing portion **74a** comprises an axial guide tube **123**, which applies force on the seal material **81a**. Substitute Specification at p. 15, ll. 3–5.

Claim 9 is dependent on claim 8 and recites that the guide tube **123** contacts the node **116** of the seal material **81a**. Substitute Specification at p. 15, ll. 3–5.

As best viewed in FIG. 8, which is a side-cross sectional view corresponding, for example, to the top half of FIG. 7, independent claim 10 provides a surgical valve **50b** comprising a first housing portion **76b** and a second housing portion **74b**, which together, define a gel cavity **78b**. Substitute Specification at p. 15, ll. 17–21. The second housing portion **74b** adjustably engages the first housing portion **76b**. Substitute Specification at p. 16, ll. 7–10. Disposed in the gel cavity **78b** is an incompressible gel **72b**. Substitute Specification at p. 15, ll. 20–21. Adjusting the position of the second housing portion **74b** relative to the first housing portion **76b** applies pressure on the gel **72b**. Substitute Specification at p. 16, ll. 10–15. Applying pressure on the gel **72b** generates a locking force on an instrument **27b** extending therethrough. Substitute Specification at p. 16, l. 21–p. 22, l. 2.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appealed claims 1, 2, and 4–10 stand rejected under 35 U.S.C. § 103(a) as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,143,853 (Abramson), in view of U.S. Patent No. 5,460,616 (Weinstein) or U.S. Patent Publication No. 2003/0139756 A1 (Brustad), and U.S. Patent No. 4,946,133 (Johnson).

The Examiner characterizes Abramson as disclosing a surgical valve comprising: a housing comprising a proximal portion **30** and a distal portion **11**; a seal material **20** made of non-compressible rubber; a proximal guide tube **14**; a distal guide tube including a portion of elements **16**, element **36**, and a portion of element **11**; a ridge **31** and groove **32**, which provide adjustability; and a Luer lock **13** coupled to the distal housing portion.

The Examiner further states that Abramson does not disclose a seal material comprising a gel. The Examiner cites FIGS. 2 and 3 of Weinstein as disclosing a surgical valve comprising a gel **30** made of silicone or petroleum jelly disposed in a gel cavity. The Examiner also cites

¶ [0033] of Brustad as disclosing a surgical valve comprising a housing; and a non-compressible seal material **54a** disposed in a gel cavity **35a**.

The Examiner characterizes Johnson as disclosing a surgical valve comprising: a housing including a proximal housing portion **27** and a distal housing portion **22**; wherein the proximal housing portion is axially adjustable to increase pressure of a seal/valve **10** on an instrument to create a locking force that tends to inhibit movement thereof.

The Examiner states that one skilled in the art would modify the device of Abramson with the gel material of Weinstein or Brustad to increase pressure on an instrument and enhance sealing.

The Examiner further states that one skilled in the art would modify the device of Abramson with the adjustable proximal housing of Johnson to create a locking force that prevents relative movement between an instrument and the valve.

The Examiner further states characterizes features such as: “for creating a pressure on an instrument extending therethrough to form a seal around the instrument” and “to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve” as both recitations of intended use as well as functional limitations. The Examiner states that such recitations do not impose any structural limitations on the claim, citing *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCCPA 1974).

The Examiner does not provide individualized analyses of each of the rejected claims.

VII. ARGUMENT

Obviousness is a question of law based on underlying factual inquiries set forth in *Graham v. John Deere*: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. Objective evidence of non-obviousness must be also considered. In assessing the differences between the claim and the cited references, every feature of the claim must be disclosed or suggested in the cited references or known to one skilled in the art in making a *prima facie* case of obviousness. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). A *prima facie* case of obviousness also requires a reasonable expectation of success in the modification or combination of references, which must be found in the cited references or must be known to one skilled in the art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

A. Independent Claims 1 and 10 Are Not Obvious Over the Cited References

For at least the reasons set forth below, independent claims 1 and 10 are allowable over the cited references.

1. Abramson Teaches Away from Increasing Pressure on a Seal Material to Form a Seal Around an Instrument

Claim 1 recites in part:

the gel having characteristics for creating a pressure on an instrument extending through the valve to form a seal around the instrument,

* * *

the proximal housing portion is adjustably movable axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument

Claim 10 recites in part:

the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument,

* * *

the second housing portion is adjustably movable axially relative to the first housing portion to increase the pressure of the incompressible gel on the instrument

Abramson discloses a fluid valve that is openable and closable, for example, for injecting or withdrawing fluids from the body. Abramson at 1:4–7 (“In injecting fluids into the body or in withdrawal of fluids therefrom using a catheter, it is frequently desirable to provide a valve in the catheter which can be opened and closed at will.”). The valve **10** is converted from the closed configuration illustrated in FIG. 1 of Abramson by inserting a male connector **40** into a female connection **14** as illustrated in FIG. 3, which bears on a valve disc **20**, converting the valve disc **20** from the closed configuration illustrated in FIG. 1A to the open configuration illustrated in FIG. 3A. Abramson at 3:65–4:13.

Applying pressure on the valve disc **20** with the male connector **40** *opens* the valve disc **20**. Consequently, one skilled in the art would understand Abramson as teaching releasing pressure on a valve disc **20** closes or seals the valve disc **20** and applying pressure opens or unseals the valve disc **20**, which is the opposite of the operation of the surgical valve of claims 1 and 10.

Moreover, this difference in operation between the valve **10** of Abramson and claims 1 and 10 define a *structural* difference therebetween, overcoming the Examiner’s characterization of certain features as recitations of intended use.

2. Abramson Does Not Disclose or Suggest a Valve That Seals with an Instrument

Claim 1 recites in part “the gel having characteristics for creating a pressure on an instrument extending through the valve *to form a seal around the instrument*”. Claim 10 recites in part “the gel having characteristics for creating a pressure on the instrument *to form a seal with the instrument*”.

As discussed above, Abramson discloses a fluid valve **10**. Abramson does not disclose or suggest that the valve **10** seals with an instrument inserted therethrough. In fact, Abramson does not discuss or suggest inserting an instrument through the valve **10** at all.

With respect to the Examiner’s contention that such features are recitations of intended use, *Pearson*, which was cited by the Examiner, stands for the unremarkable proposition that reciting an intended use of a known composition does not make a claim to the composition patentable. In the appealed claims, certain features are recited functionally. Such recitations are

not improper. M.P.E.P. 2173.05(g). “A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” *Id.* One skilled in the art would understand the cited portions of claims 1 and 10 as reciting a surgical valve with a structure that is capable of sealing with an instrument extending therethrough. Nothing in Abramson discloses or suggests a structure that seals with an instrument extending therethrough.

3. Abramson Does Not Disclose or Suggest a Locking Force Tending to Inhibit Movement of an Instrument

Claim 1 recites in part “the proximal housing portion is adjustably movable axially relative to the distal housing portion ... to create a locking force tending to inhibit movement of the instrument relative to the valve.” Claim 10 recites in part “the second housing portion is adjustably movable axially relative to the first housing portion ... to create a locking force tending to inhibit movement of the instrument relative to the valve.”

As discussed above, Abramson discloses a fluid valve **10** and does not disclose or suggest inserting an instrument through the valve **10**. Consequently, Abramson also does not disclose or suggest a locking force on an instrument as recited in claims 1 and 10.

4. Abramson Does Not Disclose or Suggest Adjustability Between a First Housing Portion and a Second Housing Portion

Claim 1 recites in part “the proximal housing portion is adjustably movable axially relative to the distal housing portion”. Claim 10 recites in part “the second housing portion is adjustably movable axially relative to the first housing portion”.

The Examiner refers to a ridge **31** and a groove **32**, which are best seen in FIGS. **4** and **5** of Abramson, as means for adjustably moving a proximal housing portion relative to a distal housing portion. FIG. **4** is an exploded view of the valve **10**. Abramson at 2:18. FIG. **5** illustrates a state of the valve **10** prior to forcible telescoping into the assembled state illustrated in FIG. **1**. Abramson at 2:19–20. Assembly is not adjustability. Nothing in Abramson discloses or suggests that the ridge **31** and groove **32** provide any adjustability between the cylindrical male member **11** and the cylindrical female member **12**. Nowhere does Abramson disclose or suggest that the valve in the configurations illustrated in FIGS. **4** or **5** is operational. Indeed, every indication in

Abramson is that the cylindrical male member **11** and the cylindrical female member **12** are not relatively adjustable.

5. Abramson Does Not Disclose or Suggest a Non-Compressible Rubber

Claim 1 recites in part “the seal material including a gel having non-compressible characteristics”. Claim 10 recites in part “a gel disposed within the gel cavity and having properties including flowability and incompressibility”.

The Examiner refers to Abramson as disclosing a seal material **20** made of rubber with non-compressible characteristics. Abramson discloses a valve disc **20** of soft rubber. Abramson at 2:40–41. Abramson does not disclose or suggest that the soft rubber is non-compressible. Many types of rubber are compressible. *See, for example*, MICHEL S. CHALHOUB, REDUCTION OF THE STIFFNESS OF RUBBER BEARINGS DUE TO COMPRESSIBILITY (U.C. Berkeley 1986); MILLARD F. BEATTY, ELASTIC STABILITY OF RUBBER BODIES IN COMPRESSION (U. Kentucky 1977).

6. Weinstein Discloses Applying Pressure to the Gel or Creating a Locking Force Tending to Inhibit Movement of an Instrument

Claim 1 recites in part:

the proximal housing portion is adjustably movable axially relative to the distal housing portion to *increase the pressure of the incompressible gel on the instrument* and to create a locking force *tending to inhibit movement of the instrument* relative to the valve.

Claim 10 recites in part:

the second housing portion is adjustably movable axially relative to the first housing portion to *increase the pressure of the incompressible gel on the instrument* and to create a locking force *tending to inhibit movement of the instrument* relative to the valve.

Weinstein discloses a spheroidal valve member **24** comprising a gel **30**, for example, a silicone gel or petroleum jelly, disposed in a fluid-filled chamber. Weinstein at 1:48–49. FIG. 3 of Weinstein illustrates a catheter **32** extending through the valve member **24**. Weinstein does not disclose or suggest applying pressure to the gel. Weinstein also does not disclose or suggest inhibiting movement of the instrument in any way. In fact, Weinstein discloses “the presence of

gel **30** provides a lubricating coating to catheter **32** and any other elongated member that passes through the catheter introducer **10**, *to facilitate the lubricity and easy advancement thereof.*" Weinstein at 3:34–37.

7. There Is No Reasonable Expectation of Success in Combining Abramson with Weinstein

The gel **30** of Weinstein is a fluid. Weinstein at 1:48–49. One skilled in the art would have no reasonable expectation of success in replacing the soft rubber valve disc **20** of Abramson with the fluid gel **30** of Weinstein. The Examiner does not explain how such a replacement is possible.

8. Johnson Does Not Disclose or Suggest Creating a Locking Force Tending to Inhibit Movement of an Instrument

Claim 1 recites in part:

the proximal housing portion is adjustably movable axially relative to the distal housing portion ... to create a locking force tending to inhibit movement of the instrument relative to the valve.

Claim 10 recites in part:

the second housing portion is adjustably movable axially relative to the first housing portion ... to create a locking force tending to inhibit movement of the instrument relative to the valve.

The Examiner relies on Johnson for disclosing a surgical valve in which a proximal housing portion **27** and distal housing portion **22** are relatively axially adjustable to increase pressure of a seal/valve **10** on an instrument to create a locking force tending to inhibit movement of the instrument. Referring to FIG. 5 of Johnson, the Examiner characterizes a cover **27** as corresponding to the proximal housing portion, a receptacle assembly **22** as corresponding to the distal housing portion, and a distal flange member **10** of a valve gasket as corresponding to the seal material. Johnson does not disclose or suggest that relative axial motion between the cover **27** and receptacle assembly **22** creates a locking force on an instrument. In fact, Johnson does not disclose a locking force on an instrument at all. Johnson also does not disclose adjusting the relative positions of the cover **27** of receptacle assembly **22**. Instead, the cover **27** simply

keeps the valve and casing member **26** in place in the receptacle assembly **22**. Johnson at 3:26–29.

9. The Examiner Does Not Cite a Disclosure or Suggestion of Retrograde Insertion of an Instrument

Claim 1 recites in part “the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal”. The Examiner does not cite any of the references as disclosing or suggesting this feature. Consequently, the rejection of claim 1 is improper for at least this reason.

10. The Examiner’s Reasons for Combining the References Are Impermissible

The Examiner proposes combining the device of Abramson with the gel material of Weinstein or Brustad to increase the pressure on an instrument and to enhance sealing characteristics. None of these references discloses or suggests the desirability of increasing the pressure on an instrument for any reason, let alone for improving sealing. The Examiner also has not taken Official Notice of this assertion. Instead, the Examiner appears to be engaging in impermissible hindsight reconstruction, using the features of the claim as a roadmap.

The Examiner proposes combining the device of Abramson with the device of Johnson in order to create a locking force for preventing movement of an instrument relative to the valve. As discussed above, neither of these references discloses or suggests this feature. The Examiner also has not taken Official Notice of this assertion. Again, the Examiner appears to be engaging in impermissible hindsight reconstruction.

B. Claims 2, 4, and 5 Are Dependent on Claim 1 and Are Also Allowable

Claims 2, 4, and 5 are dependent on claim 1, and consequently, are also allowable for at least the same reasons as claim 1, or in the alternative, as dependent on an allowable base claim. Moreover, the Examiner does not cite any reference as disclosing or suggesting the additional features recited in any of these claims. Consequently, the rejections of these claims are improper and the claims are allowable for at least this reason.

C. Independent Claim 6 Is Allowable Over the Cited References

The Examiner does not find a disclosure or suggestion of every feature recited in claim 6. Consequently, the rejection of claim 6 is improper and claim 6 is allowable for at least this reason.

Furthermore, the Examiner's objections of recitations of intended use do not apply to claim 6.

1. Claim 6 Recites a Node and an Axial Channel

Claim 6 recites in part a seal material **81a** comprising a node **116** and an axial channel **101a**. The Examiner does not identify any disclosure or suggestion of either a node or an axial channel in any of the cited references.

2. Claim 6 Recites an Axial Channel in an Open State

Claim 6 recites in part the axial channel **101a** in an open state. The Examiner does not identify any disclosure or suggestion of an axial channel in an open state in any of the cited references.

3. Claim 6 Recites a Force Sufficient for Placing the Axial Channel in a Closed State

Claim 6 recites in part a second housing portion **74a** applying a force to the seal material **81a** sufficient to place the axial channel **101a** in a closed state. The Examiner does not identify any disclosure or suggestion of the cited feature in any of the cited references.

4. Abramson Teaches Against the Subject Matter of Claim 6

As discussed above, the valve disc **20** of Abramson actually exhibits a behavior opposite of the subject matter of claim 6. In the absence of the male connector **40**, the valve disc **20** is closed, whereas, applying pressure to the valve disc **20** with the male connector **40** opens the valve disc **20**.

5. The Examiner's Reasons for Combining the References Are Irrelevant to Claim 6

As discussed above, the Examiner's reasons for combining the references invoke the interaction between a valve and an instrument. Because claim 6 does not recite an instrument,

Application No. 10/695,295
Notice of Appeal filed September 11, 2009
Appeal Brief filed November 12, 2009

these reasons are irrelevant to claim 6. Consequently, the rejection is improper and claim 6 is allowable for at least this reason.

D. Claims 7-9 Are Dependent on Claim 6 and Are Also Allowable

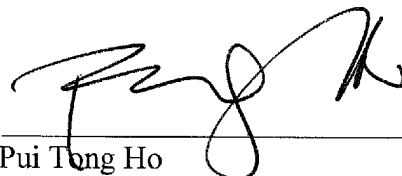
Claims 7-9 are directly or indirectly dependent on claim 6 and are allowable for at least the same reasons as claim 6, as well as because these claims are dependent on an allowable base claim. Furthermore, the Examiner does not identify a disclosure or suggestion in any reference of the combination of additional features recited in these claims. Consequently, the rejections of these claims are improper and the claims are allowable for at least this reason.

E. Conclusion

Because each of the outstanding rejections of the appealed claims is improper, Applicant requests that the Board find all appealed claims allowable over the references of record.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 01-2215.

Respectfully submitted,
APPLIED MEDICAL RESOURCES

BY 
Pui Tong Ho
Registration No. 44,155
Telephone: (949) 713-8383

VIII. CLAIMS APPENDIX

The following is a listing of the claims on appeal.

1. (Previously presented) A surgical valve having an axis extending between a proximal end and a distal end, comprising:

a housing including a proximal housing portion and a distal housing portion adjustably cooperating with the proximal housing portion to define a gel cavity;

a seal material disposed in the gel cavity, the seal material including a gel having non-compressible characteristics, the gel having characteristics for creating a pressure on an instrument extending through the valve to form a seal around the instrument;

a proximal guide tube extending axially proximally from the proximal housing portion;

the proximal guide tube facilitating insertion of a surgical instrument into the seal material; and

a distal guide tube extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal, wherein the proximal guide tube includes exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion, wherein

the proximal housing portion is adjustably movable axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.

2. (Original) The surgical valve recited in Claim 1, further comprising:

a Luer lock coupled to the distal housing portion; and

the distal guide tube being included within the Luer lock.

3. (Canceled)

4. (Original) The surgical valve recited in Claim 1, wherein:

the seal material defines an axial channel through the gel; and

the proximal guide tube contacts the seal material around the axial channel at the proximal end of the valve.

5. (Previously presented) The surgical valve recited in Claim 1, wherein:
the seal material and the distal housing portion form a subassembly free of a circumferential seal between the seal material and the distal housing portion; and
the proximal guide tube applies a force to the seal material in the subassembly to form a circumferential seal between the gel and the distal housing portion.

6. (Original) A surgical valve, comprising:
a first housing portion defining a gel cavity;
a seal material including a gel and having a node and an axial channel;
a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; and
a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state.

7. (Original) The surgical valve recited in Claim 6, wherein the second housing portion applies the force to the seal material with a magnitude sufficient to create a circumferential seal between the seal material and the first housing portion.

8. (Original) The surgical valve recited in Claim 7, wherein the second housing portion includes an axial guide tube, and the guide tube applies the force to the seal material in the subassembly.

9. (Original) The surgical valve recited in Claim 8 wherein the guide tube contacts the node of the seal material to apply the force to the seal material.

10. (Previously presented) A surgical valve adapted to form a seal around a surgical instrument extending through the valve, comprising:
a first housing portion;
a second housing portion adjustably engaging the first housing portion and defining with the first housing portion a gel cavity having a volume;

a gel disposed within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument, wherein the second housing portion is adjustably movable axially relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.

11. (Withdrawn) The surgical valve recited in Claim 10 wherein the first housing portion and the second housing portion comprise:

complimentary screw threads disposed on the first housing portion and the second housing portion, the screw threads facilitating axial movement of the first housing portion relative to the second housing portion to reduce the volume of the gel cavity and to create the locking force between the incompressible gel and the instrument.

12. (Withdrawn) The surgical valve recited in Claim 11, further comprising:
a first tab fixed to the first housing portion;
a second tab fixed to the second housing portion;
the first tab and the second tab forming a first tab pair moveable relative to each other to decrease the volume of the gel cavity.

13. (Withdrawn) The surgical valve recited in Claim 12, further comprising:
a third tab fixed to the first housing portion;
a fourth tab fixed to the second housing portion;
the third tab and the fourth tab forming a second tab pair moveable relative to each other to increase the volume of the gel cavity.

14. (Withdrawn) The surgical valve recited in Claim 13, wherein the first valve pair is disposed on a side of the valve opposing the second tab pair.

15. (Withdrawn) The surgical valve recited in Claim 13 wherein the fourth tab of the second tab pair is integral with the second tab of the first tab pair.

Application No. 10/695,295
Notice of Appeal filed September 11, 2009
Appeal Brief filed November 12, 2009

16-25. (Canceled)

Application No. 10/695,295
Notice of Appeal filed September 11, 2009
Appeal Brief filed November 12, 2009

IX. EVIDENCE APPENDIX

The following U.S. Patents are relied on as evidence in this appeal: U.S. Patent No. 4,143,853 (Abramson); U.S. Patent No. 5,460,616 (Weinstein); U.S. Patent Publication No. 2003/0139756 A1 (Brustad); U.S. Patent No. 4,946,133 (Johnson). Abramson was first cited by the Examiner in an Office Action dated December 24, 2008. Weinstein was first cited by the Examiner in an Office Action dated August 25, 2006. Brustad and Johnson were first cited by the Examiner in an Office Action dated May 15, 2009.

Application No. 10/695,295
Notice of Appeal filed September 11, 2009
Appeal Brief filed November 12, 2009

X. RELATED PROCEEDINGS APPENDIX

There are no related proceedings.